K052897

NOV - 8 2005

Attachment B:

Summary of Safety and Effectiveness
Prepared in accordance with 21 CFR Part 807.92(c).

GE Healthcare Technologies

General Electric Company
P.O. Box 414, Milwaukee, WI 53201

Submitter: GE Healthcare Technologies
PO Box 414
Milwaukee, WI 53201

Contact Person: Mark Stauffer
Safety and Regulatory Engineering
Telephone: 262-544-3217 Fax: 262-548-2032

Date Prepared: October 5, 2005

Device Name: GE Definium AMX 700
Mobile X-ray System, 21 CFR 892.1720, 90 IZL

Marketed Device: GE AMX-4+ Mobile X-ray System, currently in commercial distribution.

Device Description: The GE Definium AMX 700 is a mobile x-ray system that enables the capture of radiographic images via a tethered digital detector or traditional film cassettes.

Indications for Use: The Definium AMX 700 is indicated for use in generating radiographic images of human anatomy. This device is not intended for mammographic applications.

Comparison with Predicate Device: The Definium AMX 700 is substantially equivalent to the currently marketed GE AMX-4+ mobile x-ray system. It utilizes similar technology and materials, and is comparable in key safety and effectiveness features. It uses the same basic design and construction and has similar weight and power requirement. It has the same intended uses as the predicate device.

Summary of Studies: The device has been evaluated for electrical, mechanical, and radiation safety, and conforms with applicable medical device safety standards.

Clinical Tests: None required. This product is a combination of two devices already cleared for the US market via 21 CFR Part 807.

Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. Intended uses and fundamental scientific technology are the same as the legally marketed GE AMX-4+ mobile x-ray system. The design and development processes of the manufacturer conform with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with factory surveillance. Therefore, it is the opinion of GE Medical Systems LLC that the Definium AMX 700 is substantially equivalent with respect to safety and effectiveness to the unmodified GE devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 2005

Mr. Mark Stauffer
Safety & Regulatory Engineering
GE HEALTHCARE TECHNOLOGIES
Post Office Box 414
MILWAUKEE WI 53201

Re.: K052897
Trade/Device Name: GE Definium AMX 700
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: October 5, 2005
Received: October 14, 2005

Dear Mr. Stauffer

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registrations, listing of devices, good manufacturing practice, labeling and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advices that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of he Act or any Federal statues and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K052897

Device Name: Definium AMX 700

Indications for Use

The Definium AMX 700 X-Ray Unit is indicated for use in generating radiographic images of human anatomy. It is intended for general-purpose diagnostic procedures. It is capable of generating radiographic images on film or digitally. This device is not intended for mammographic applications.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use V
(Per 21 CFR 801-109)

OR Over-The-Counter Use_____

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052897